U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT EM-ARC-98-13

OF THE

U. S. DEPARTMENT OF ENERGY
OFFICE OF WASTE MANAGEMENT
OFFICE OF EASTERN OPERATIONS
AND
OFFICE OF PROGRAM INTEGRATION

GERMANTOWN, MARYLAND

JUNE 1 THROUGH JUNE 4, 1998

Prepared by:_____ **Date:**_____
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Approved by:_____ **Date:**_____
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1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit EM-ARC-98-13, the audit team determined that the Department of Energy (DOE), Office of Waste Management, Office of Eastern Operations (EM-32) and Office of Program Integration (EM-37), with the exception of areas where deficiencies exist, are satisfactorily implementing applicable portions of the QA Program described in the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 7, and EM-32 Standard Practice Procedures (SPP) for High-Level Waste. QA Program Elements 1.0, 2.0, 5.0, 6.0, 16.0, 17.0, 18.0, and Appendix A were found satisfactory by the audit team. QA Program Elements 3.0, 4.0, 7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0, Supplements I, II, III, IV, V, Appendix B and C were determined not to be applicable to EM-32/37 headquarters high-level waste activities.

EM-32/37 have performed an impact evaluation and have determined that QARD, Revision 8, has no impact on EM-32/37 headquarters high-level waste activities.

The audit team identified three deficiencies during the course of the audit that resulted in the issuance of two Deficiency Reports described in Section 5.5.2 of this report. In addition, there were three deficiencies identified by the audit team that were corrected during the audit. These conditions are described in Section 5.5.4 of this report.

2.0 SCOPE

The audit was conducted to evaluate the adequacy, compliance, and the effectiveness of EM-32/37 in implementing the QA Program as described in the QARD and the EM-32 SPPs for high-level waste activities.

The following QA Program Elements/Requirements were evaluated during the audit, in accordance with the approved audit plan.

QA PROGRAM ELEMENTS/REQUIREMENTS

1.0	Organization
2.0	Quality Assurance Program
5.0	Implementing Documents
6.0	Document Control
16.0	Corrective Action
17.0	Quality Assurance Records
18.0	Audits
Appendix A	High-Level Waste Form Production

The following QA Program Elements/Requirements were not reviewed during the audit because they are not applicable to the EM-32/37 headquarters scope of work:

3.0	Design Control
4.0	Procurement Document Control
7.0	Control of Purchased Items and Services
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
12.0	Control of Measuring and Test Equipment
13.0	Handling, Storage and Shipping
14.0	Inspection, Test and Operating Status
15.0	Nonconformances
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement IV	Field Surveying
Supplement V	Control of the Electronic Management of Data
Appendix B	Storage and Transportation
Appendix C	Mined Geologic Disposal System

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members and observers and their assigned areas of responsibility:

Name/Title/Organization	QA Program Elements/Requirements, Technical Areas, Processes, Activities or End-Products
Richard L. Maudlin, Audit Team Leader, OQA	QA Program Elements 2.0, 5.0, 6.0, 18.0 and Appendix A
Gary D. Wood, Auditor, OQA	QA Program Elements 1.0, 2.0, 16.0, and 17.0

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held at the EM-32/37 offices in Germantown, Maryland on June 1, 1998. A daily debriefing and coordination meeting was held with the EM-32/37 management. The audit was concluded with a post-audit meeting on June 4, 1998. Personnel contacted during the audit are listed in Attachment 1. The list includes those who attended the pre-audit and post-audit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, for the program elements that have been implemented, the QA Program is adequate and is being satisfactorily implemented by EM-32/37 for the scope of this audit. The results for each program element evaluated are contained in Attachment 2, Summary Table of Audit Results.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no stop work orders, immediate corrective actions or related additional items resulting from this audit.

5.3 QA Program Audit Activities

A summary table of audit results is provided in Attachment 2. The audit checklists contain the details of the audit evaluation along with identification of the objective evidence reviewed. The checklists are maintained as QA Records.

5.4 Technical Audit Activities

There were no technical activities evaluated during the audit.

5.5 Summary of Deficiencies

The audit team identified three deficiencies during the audit for which two Deficiency Reports (DR) have been issued. Three additional deficiencies were identified and corrected during the audit.

Synopsis of deficiencies documented as DRs and the three corrected during the audit are detailed below. The DRs have been transmitted under a separate letter.

5.5.1 Corrective Action Requests (CAR)

None

5.5.2 Deficiency Reports

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A review of training/qualification/certification files revealed that records were missing for three personnel who had participated in the performance of audits in support of EM-37 and one individual was missing records for the self study of SPPs. Also, SPP 3.01 and 3.02 are not clear on who has responsibility for the maintenance of training/qualifications records and where these types of records are to be maintained for personnel external to EM 32/37.

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A QA Specialist, designated as an audit team leader, reviewed a corrective action document package for which he had performed the follow-up verification. As a result, auditor independence was compromised by this action.

Internal and external audit reports identified conditions adverse to quality as observations/concerns. The only process in the SPPs for addressing conditions adverse to quality is the Deviation and Corrective Action Report (DCAR) process.

5.5.3 Performance Reports

None

5.5.4 Deficiencies Corrected During the Audit

Deficiencies which are considered isolated in nature and only require remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. A Review Comment Record (RCR) completed by a HLW Team Leader on 10/27/97 for the review of SPP 3.01, Revision 1 had two comments which were to be incorporated in the procedure as agreed upon in the RCR disposition. Only one of the two comments was incorporated in the SPP. The second comment was not incorporated as required by SP 4.04, Revision 1.

   Prior to the completion of the audit, the HLW Team Leader who originated the comments, corrected the RCR by

deleting the one comment which was not incorporated into the procedure. Both the person who made the comment and the dispositioner agreed that the comment was inappropriate. A copy of the corrected RCR was sent to the records center.

2. An attachment to a letter from D. Lynch to J. Conway which transmitted the response to DCAR 97VP-SR-AU-01-D01 was not included in the records package as required by the SPP 7.01, Revision 0. Prior to the completion of the audit, the missing attachment was located and placed in the records package.

3. Copies of Internal Audit Report 97EA-IN-AU-01 and External Audit Report 98VP-SR-AU-01 had not been distributed to all of the organizations/individuals as required by SPP 4.02, Revision 1. Prior to completion of the audit, evidence was provided that copies of the referenced audit reports had been properly distributed as required by the SPP.

6.0 RECOMMENDATIONS

None

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Result

ATTACHMENT 1

PERSONNEL CONTACTED DURING THE AUDIT

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
James Conway	HLW QAPM	X	X	X
Gerry Camasta	CRF Supervisor	X	X	X
Kris Grisham	QA Specialist	X	X	X
Mark Rawlings	WV Team Leader	X		
Ralph Erickson	Director, EM-32	X	X	X
Kurt Fisher	SR Program Mgr	X		X
Louis Sirianni	QA Specialist	X		
James Antizzo	Director, EM-37	X		
Nancy Roy	Lead Records Splst	X		
Ken Picha	HLW-Type Manager	X		X
Hank Himpler	Safety and Health	X		

ATTACHMENT 2
AUDIT EM-ARC-98-13 DETAIL SUMMARY AUDIT RESULTS

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEW	CHECKLIST PAGES	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1.0	SPP 1.02, REV. 1	pgs. 1-2			SAT	SAT	SAT
2.0	SPP 2.01 REV. 1	pgs. 5-7			SAT	SAT	SAT
	SPP 3.01 REV. 1	pgs. 8-12	EM-ARC-98-D-102		SAT	SAT	
	SPP 3.02 REV. 0	pgs. 13-14	EM-ARC-98-D-102		SAT	SAT	
	SPP 8.01 REV. 0	pgs. 3-4			SAT	NI	
5.0	SPP 4.04 REV. 1	pgs. 20-24	CDA #1		SAT	SAT	SAT
6.0	SPP 6.01 REV. 0	pgs. 25-27			SAT	SAT	SAT
16.0	SPP 5.01 REV. 0	pgs. 28-29			SAT	SAT	SAT
	SPP 5.02 REV. 0	pg. 30-31			SAT	SAT	SAT
17.0	SPP 7.01 REV. 0	Pgs. 32-35	CDA #2		SAT	SAT	SAT
18.0	SPP 4.01 REV. 0	pgs. 36-37			SAT	SAT	SAT
	SPP 4.02 REV. 1	pgs. 38-41	CDA #3 EM-ARC-98-D-103		SAT	SAT	
	SPP 4.03 REV. 0	pgs. 15-19			SAT	NI	
APPEND. A	MOA 05/23/95	pgs. 42			SAT	SAT	SAT

LEGEND:

CDA	Corrected During Audit
NI	Not Implemented
SAT	Satisfactory